PATENT
Attorney Docket No.: VITA1120-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Triglia and Purchio	Art Unit: 1632
Application No.:	10/723,590	Examiner: Shin Lin Chen
Filed:	November 25, 2003	Conf. No. 7574
Title:	C3A SERUM FREE CLONAL CELL LINE AND METHODS OF USE	

Mail Stop:AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER RULE 132

JOHN BROTHERTON DECLARES AS FOLLOWS:

1. I am the Vice President of Technology & Product Development at Vital Therapies, Inc., Vital Therapies, Inc. being the assignee of the above referenced patent application, and I am familiar with the subject matter as disclosed and claimed in said application. I have a Ph.D. in Chemical Engineering from the University of California, San Diego, and have an expertise in the design of hollow fiber bioreactors for support of mammalian cell growth.

2. I understand that the examiner of record has taken the position that the claims do not meet the enablement standard under 35 U.S.C. §112, first paragraph.

3. I am aware of past and on-going clinical investigations being conducted with patients receiving treatment with an extracorporeal liver assist device (ELAD®) system, which system is described in the above reference and embraced as claimed.

4. I submit that a randomized, open-label Phase I clinical trial in critically ill patients with late stage Fulminant hepatic failure (FHF) or primary graft non-function was competed in the third quarter of 2000. Patients were enrolled at six transplant centers with the goal of evaluating the safety and effectiveness of the ELAD® system in bridging patients to either

transplantation or recovery. Patients received ELAD® system treatment continuously for 3-168 hours (7 days).

5. I submit that the results showed the following: (i) satisfactory biocompatibility, ii) improved hemodynamic parameters, and iii) improvement in encephalopathy, which indicated that patients could safely be removed from ELAD® system treatment. Further, outcomes comparing ELAD® system-treated patients to control patients showed 12 of 15 (80%) ELAD® system-treated patients successfully bridged to transplant or recovery, compared to 5 of 9 (56%) in the control group. Moreover, in a subset of the trial, including only those patients who were listed for transplant, 11 of 12 (92%) of the ELAD® system-treated patients were successfully bridged to transplant or recovery versus 3 of 7 (43%) of the listed controls.

6. I submit that these results demonstrate that ELAD® system treatment appears to increase the rate of recovery from sublethal acute liver failure, and has the capacity to support patients for several days (even in the presence of severe liver failure), serving as an effective bridge to transplantation.

7. All statements made in the Declaration of our (my) own knowledge are true and all statements made in this Declaration on information and belief are believed to be true, and these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and may jeopardize the validity of this application or any patent issuing therefrom.

Date: 22 Feb 2007
February 22, 2007

John Brotherton, Ph.D.